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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/997,822 | 11/30/2001 | Daniel R. Boggs | F-5366 DIV | 5410 |
| 7: | 590 10/14/2003 | | EXAM | INER |
| Michael C. Mayo | | | FORTUNA. ANA M | |
| Baxter Healthcare Corporation Fenwal Division, RLP-30 | | | ART UNIT | PAPER NUMBER |
| P.O. Box 490 - Route 120 & Wilson Road | | | 1723 | |
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DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|
| | 09/997,822 | BOGGS ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Ana M Fortuna | 1723 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| 1) Responsive to communication(s) filed on 30 N | lovember 2001 . | | | | | |
| 2a)☐ This action is FINAL . 2b)⊠ Th | s action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>12-36</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)⊠ Claim(s) <u>34-36</u> is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>12-26 and 28</u> is/are rejected. | | | | | | |
| 7) Claim(s) 27 and 29 is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |
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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 12-19, 21, 22, are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (4,728,432)(hereinafter '432). '432 discloses the process of making the membrane and the membrane having layer at both sides of the support made form a polymeric material containing a particulate material (adsorbent) (abstract, column 2, lines 1-66). The method of making the membrane from polymer containing the adsorbent and the specific polymers as listed in claim 2, e.g. polyurethane, is disclosed in '432 (column 3, lines 29-50). Fixing the membrane at both sides of the support is disclosed in column 4, lines1-12, of the reference above.

As to claims 14-15, hydrophobic polymers are disclose in reference '432, e.g. polyurethane, polysulfone, polyethylene, etc. (column 3, lines 46-51); the uniformly dispersing the support in the polymer and the final membrane and uniform thickness ranging from 10 to 400 micrometers, is also disclosed (column 3, lines 57-65). As to claims 16, 17, the polymer adsorbent (particulate) composition is also disclosed in '432 (column 3, lines 51-56). Regarding claim 18, dissolving the polymer in a solvent, and further mixing the particles or particulate with the polymer solution is disclosed in '432

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(column 5, lines 2-14). As to claims 19, 21, 22, dipping the membrane in water as non-solvent is further disclosed (column 5, lines 14-20), removing it from the water (e.g. for further treatment with hot water), is also disclosed; the term drying is not disclosed, however, is inherent of the process.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 31, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al (4,728,432)(hereinafter '432). '432, discussed above, fails to disclose the membrane as pleated or rippled sheet. However, teach using the membrane of his invention by rolling or superimposing it into multiple layers and housing it into a vessel, which suggests the membrane as flexible. It would have been obvious to one skilled in the art at the time the invention was made to adapt the membrane of '432 in a folded or rippled structure, e.g. to provide larger membrane surface area.
- 5. Claims 20, 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al (4,728,432)('432) as applied to claim12 above, and further in view of Pacheco et al (6,126,826)(hereinafter '826). Reference '432 discussed above, fails to disclose moving the support during the process of making the membrane. '432, however, teaches making the membrane by conventional methods (column 3, second paragraph). '826 teaches making membranes on a support by continuously moving the

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support, providing a coating of PVDF membrane on at least one surface of the support, or encapsulating the support on the membrane (abstract, column 9, lines 64-68, column 10, lines 1-9, and lines 46-46-60, and column 15, last paragraph bridging column 16, lines 1-6). It would have been obvious to one skilled in the art at the time the invention was made, to make the membrane, including coating of both surfaces to encapsulate the support, as disclosed in both references, by any method, e.g. dip coating, spraying both surfaces of the membrane, or by the method of '826, which includes continuously moving the support and moving the support in the coating solution of the polymer. It would have been further obvious at the time the invention was made to make the membrane by the method of '826, and further add adsorbent particles to the polymer mixture, since '432 teaches adding adsorbent to a membrane made by phase inversion, to made the membrane more suitable for filtration of body fluids. As to claim 23, '432 fails to disclose specific drying temperature. '826 teaching drying a PVDF membrane at temperatures between 0 to 100 degree C, since the polymer has a melting point of 160 degree C. Reference '432 teach polyurethane and cellulosed materials for the membrane, to which Applicants admits, e.g. claim 2, to be equivalents for the membrane process.

6. Claims 24-26, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al. as applied to claim12 above, and further in view of Mahendran et a. (5,916,039)('039). Post-treatment of the membrane is not disclosed in reference '432. Reference '039 teaches. Treating a PVDF membrane containing particulate with a hydrophilic polymer, e.g. PVA (column 2, lines 57-68, column 3, lines 40-43). It

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would have been obvious to one skilled in the art at the invention was made to treat the membrane of '432, with a hydrophilic agent, e.g. PVA or equivalent, to improve membrane properties, as suggested in '039).

7. Claims 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al (4,728,432)('432) in view of Kopacienwicz et al (6,200,474 ('474). '432, discussed above, fails to disclose making the membrane including disposing the support and the polymer and particulate blend within a housing, to apply the blend onto the support. 474 teaches a membrane made within a housing and on a support disposed within the housing, the membrane is made from a blend of a polymer and a particulate, e.g. adsorbent material, the list of suitable polymers is also disclosed, e.g., polysulfone, cellulose acetate, PVDF, etc. (abstract, column 3, lines 16-20, column 4, lines 41-68, column 5, lines 1-4). It would have been obvious to one skilled in the art at the time the invention was made to form a membrane made from a polymer and particles on a support as disclosed in '432, and further made the membrane within a housing, as suggested in '474, since both references teach the same polymer and particulate, e.g. polysulfone, and activated carbon, and are intended for the same use, e.g. biological fluids filtration. Coating the membrane on both surfaces of the support in the process including making the membrane within a housing (pipette), it would have been obvious to one skilled in the art at the time the invention was made, based on the teaching of '432.

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Allowable Subject Matter

- 8. Claims 27, 29 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.
- 8. Claims 34-36 are allowed.
- 9. The following is a statement of reasons for the indication of allowable subject matter. The process of making the membrane the membrane as claimed n claim 34-36, including advancing the support at the particular claimed rate, is not suggested in the prior art of record. Claims 27 and 29, including post-treating the membrane with sodium chloride, is also not suggested in the prior art of record.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References 6,153,666B2, 6,090,441, 6,126,826 have been cited as teaching continuous processes of making membranes, e.g. from PVDF, coated on both surface, e.g. with the support embedded within the membrane layers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on 9:30-6:00 M-F.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (703) 308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Ana M Fortuna Primary Examiner Art Unit 1723

AMF